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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/167,080 10/06/98 EATON

L 8793-41592

IM22/1115

EXAMINER

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LEE, D

ART UNIT

PAPER NUMBER

1732

DATE MAILED:

11/15/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/167,080

Applicant(s)  
Eaton

Examiner  
Dae Lee

Group Art Unit  
1732



☒ Responsive to communication(s) filed on Oct 6, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-18 is/are pending in the application.  
Of the above, claim(s) 10-18 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-18 are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2-3

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. Turning the breast prosthesis inside out (claims 1-9);
- b. Turning flexible sheet inside out (claims 10-18).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are found to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Charles Dougherty on November 3, 1999 a provisional election was made without traverse to prosecute the invention of Species a, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-18 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

#### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: on page 14, line 21 "flashing 22". Correction is required.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyman (USPN 3021569) in view of the admitted prior art as set forth in the instant specification, pages 2-11, and Wright *et al* (USPN 2580264). Lyman teaches the basic claimed method of vacuum-forming a mold, the steps of the method comprising:

- a. Vacuum-forming a uniformly flat and flexible sheet over a positive model (Fig. 14; col 2, ln 23-64);
- b. Casting a solid article such as a mold from the flexible sheet (col 2, ln 65-72).

Lyman does not disclose producing a positive model. However, the Applicant discloses producing a three-dimensional image of a breast by performing a computerized scan of the breast using a camber on a 180 degree mount is well known in the art (pg 10, ln 10-14). Applicant discloses that the breast is held in a half-cup fitted underneath the breast (pg 4, ln 7-8). Applicant does not disclose that forming a positive model of the breast based on the three-dimensional image using a computer-controlled milling machine is known. However, forming a positive model using a computer-controlled milling machine is well established and well known in the art of computer aided modeling. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the well known idea of forming a positive model from a three-dimensional image through the use of a computer-controlled milling machine with the

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method of forming a breast prosthesis as disclosed in the instant specification in order to develop a highly accurate and reproducible model.

Lyman does not teach introducing a curable material into the mold to form a breast prosthesis outer surface. However, Wright *et al* do teach introducing a curable material into the mold to form the breast prosthesis outer surface and then turning the breast prosthesis outer surface inside out (col 3, ln 60-75). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Wright *et al* with the method of Lyman in order to form a breast prosthesis from the accurate mold obtained from vacuum molding.

Lyman does not teach the thickness of the plastic sheet to be 1.27 millimeters. Lyman does not specifically teach 1.9 millimeters. However, the thickness of 1.9 millimeters are well known in the art and it would have been obvious to one of ordinary skill in the art at the time of the invention to use the 1.9 millimeters obtained from routine experimentation with the method of Lyman in order to obtain a breast prosthesis with the desired durability and feel.

Lyman also does not teach using Silastic as a curable material. However, Silastic is notoriously well known in the art of breast prosthesis formation. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the well known Silastic with the method of Lyman in order to form a breast prosthesis which is resilient yet soft to the touch.

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*Conclusion*

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fukao (USPN 5169578) teaches forming a slip casting mold from a master mold. Gillman (USPN 2508156) teaches making a mirror-image prosthesis. Leitzel (USPN 3065511) and Griffin (USPN 5108686) both teach the general state of the art.

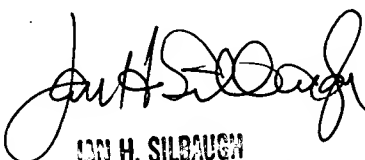
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dae Young Lee whose telephone number is (703) 305-0393. The examiner can normally be reached on Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jan H. Silbaugh, can be reached on (703) 308-3829. The fax phone number for this Group is (703) 305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

DYL

November 8, 1999

  
JAN H. SILBAUGH  
SUPERVISORY PATENT EXAMINER  
ART UNIT 1732  
11/08/99